



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/850,061 | 05/08/2001 | Christer Nordstedt | 033315-002 | 1927 |

7590 07/30/2002

Benton S. Duffett, Jr.
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER

BORIN, MICHAEL L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1631 | 6 |

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/850,061

Applicant(s)

Nordstedt et al.

Examiner
Michael Borin

Art Unit
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-37 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 1-37 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

Art Unit: 1631

Part III DETAILED ACTION

Pursuant to Preliminary amendment filed 5/8/01, claims 22-37 are added.

Claims 1-37 are pending.

Please note that claims 11-26 are in "use" format". For the purposes of the foregoing restriction requirement, the claims are addressed as drawn to methods of use.

Restriction/Election Requirement.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, 19, 25, 26 (in part) drawn to linear peptide of formula (I), classified in class 530, subclasses 329, 330.
- II. Claims 11-18, 27, 28, 32, 33, 34 (in part) drawn to method of use of peptides of formula (I) to inhibit polymerization of amyloid peptide, classified in class 514, subclass 02 + .
- III. Claims 20-24, drawn to method of use of peptides of formula (I) in manufacturing a medicament, classified in class 514, subclass 02 + .

- IV. Claim 29, drawn to method of use of peptides of formula (I) to identify an organic compound classified in class 435, subclass 7.1.
- V. Claim 30, drawn to method of use of peptides of formula (I) to screen a compound library, class 435, subclass 7.1.
- VI. Claim 31, drawn to method of use of peptides of formula (I) to detect amyloid deposits by positron emission tomography, classified in class 424, subclass 9.4.
- VII. Claim 35, drawn to method of use of peptides of formula (I) to treat demens, classified in class 514, subclass 02 + .
- VIII. Claim 36, drawn to method of use of peptides of formula (I) to treat cerebral hemorrhage, classified in class 514, subclass 02 + .
- IX. Claim 37, drawn to method of use of peptides of formula (I) to prevent fibril formation classified in class 514, subclass 02 + .
- X. Claims 1-10, 19, 25, 26 (in part) drawn to cyclic peptide of formula (I), classified in class 530, subclass 317.

Art Unit: 1631

The inventions are distinct, each from the other because of the following reasons:

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: First, there is no common core structure necessary for the common utility for the compounds encompassed by the product claims. The only structural characteristic, amino acid residue Leu in the formula (I) of claim 1 is not sufficient to constitute the core structure of 4-15 amino acid long peptide as claimed. Second, the compounds encompassed by claim 1 are not a contribution over the prior art because they are suggested by references readily available in the prior art. For example, peptides of the sequence GFLGFL (i.e., comprising FLGF sequence), which read on the instantly claimed peptides of formula (I), are taught by Keilova et al (Eur. J. Biochem., 1968, 4, pages 442-447. Therefore, the lack of unity is present because the linking technical feature is not a "special technical feature" as defined by PCT Rule 13.2. Where inventions are related as disclosed but are distinct as claimed, restriction may be proper. (MPEP 806). It is proper for the Office to refuse to examine that which applicants regard as their invention, if the subject matter in a claim lacks unity of

Art Unit: 1631

invention, *In re Harnish* , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi* , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention does not exist where compounds included within a Markush group (1) do not share a common utility and (2) do not share a substantial structural feature disclosed as being essential to that utility. (MPEP 803.02)

Cyclic peptides of Group X are independent and/or patentably distinct from the linear peptides of Group I because they have different structure, different classification, and peptides of Group X would be expected to possess distinctly different structure, and/or physico-chemical properties, and/or capable of separate manufacture and/or use.

Inventions I and II-IX are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of use can be practiced with a broad variety of drugs beyond the claimed peptides. Further, methods II-IX are alternate methods of using the compounds of

Art Unit: 1631

Group I. Further, the products as claimed can be used in a materially different processes such as peptide synthesis.

Methods of Groups II-IX are independent and/or distinct because they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. For example, a method of inhibiting polymerization of amyloid peptide is independent from method of screening peptide library; methods of treatment of distinct disorder conditions of groups are patentably distinct because the disorder conditions are not immediately related to each other, have different mechanisms of development and etiology, and the methods of treatment have different enablement requirements; methods of screening of Groups IV and V require different steps (detecting ability to inhibit polymerization for Group IV vs detecting the ability to bind specific residues of polypeptide in Group V. The Groups require different literature search and a reference teaching one method, e.g., treatment of hemorrhage, will not teach treatment of any other disorder e.g., preventing demens, or will not teach screening a product library. If one of method Groups II-IX is elected, further restriction to groups, as set forth for groups I and X is required.

Art Unit: 1631

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. (MPEP 821.04)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied

Art Unit: 1631

by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Species Requirement

Election of species should be required prior to a search on the merits in all applications containing both species claims and generic or Markush claims.(MPEP 808.01(a))

Upon election of any single one of the Groups from above the following election of species is hereby required for the initial search for examination on merits:

The claims of Groups are generic to a plurality of disclose patentably distinct species of peptides that require a burdensome classification, and/or bibliographic, manual and computer search. Accordingly, regardless of which group is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e., a single compound), even though the requirement is traversed. Applicant should include a chemical structure (or sequence) of the elected compound if not already contained in the specification.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

Art Unit: 1631

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

To be complete, a response to the election of species requirement should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added. MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

